Ciguatera Diagnostic Method Study—Consent Form

For use by Physicians Associated with the University of Miami/Jackson Memorial Hospital, Miami, Florida

Background
The Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia and the United States Food and Drug Administration (FDA) in Dauphin Island, Alabama are collaborating on a research study with the University of Miami to find new tests for ciguatera (*pronounced "si gwah the' rah"*) fish poisoning in people. Some ocean plants make ciguatera poison. When fish eat the plants, the poison builds up in the fish. If people eat the fish, they get ciguatera poisoning. Now there is no way to test people for ciguatera poisoning.

Your doctor thinks you have ciguatera fish poisoning. We want you to be part of our research study. We are running this study to find a new test for ciguatera poisoning. The CDC is leading this study. FDA will be testing the blood and urine.

Procedures
If you agree to be part of this study, your doctor will get about four teaspoons of blood and urine samples while he or she treats you for ciguatera. We will use it to see if a new test for this poison works. These specimens will be marked with only a code number to protect your privacy. We will not know who you are and so cannot give you your test results. These tests will not help you because they are research tests and we don't know if they work.

We also want to save the leftover blood and urine to see if other tests for this poison work. Again, these leftover specimens will be saved using only a number by FDA. You can still be part of this study even if you do not want your urine or blood to be saved.

Benefits
There is no benefit to you to be part of this study. But by being part of this study, you may help us find a test to diagnose ciguatera in people. You will not have to pay for this procedure. We will not pay you for your blood and urine.

Compensation
If we find a good test for ciguatera, you will not get any money from the sale or use of the new test.

Risks
It might hurt a little to have blood drawn. Afterwards it may bleed or get infected. You might get a bruise or a lump where the blood was taken. Some people faint when they have blood taken. Other risks of blood drawing include the occurrence of temporary discomfort and/or bruise at the site of puncture; rarely, infection or the formation of a small clot or swelling to the vein and surrounding area may occur.

Nothing special will be done to get urine from you for this study. You will be urinating into a plastic container or bag. You might be uncomfortable doing this.

If you are harmed as a result of being in this study, treatment will not be provided by CDC, the University of Miami, or Jackson Memorial Hospital. These institutions do not normally pay for harm done to you as a result of being in a research study. Thus, you (or your insurer, Medicare, or Medicaid) will have to pay for any care that is needed. However, by signing this consent form and agreeing to be in this study, you are not giving up any of your rights. If you believe that you have been harmed, please contact CDC Deputy Director for Science's office at 1-800-584-8814. Please leave your name, phone number and that you are calling about CDC Protocol #3792. Someone will call you back as soon as they can with information on your rights and advice on how to proceed.

Confidentiality
We might write about what we learn from this study. If we do, unless you express your permission for us to do so, we will not use your name or anything that identifies you. All information and specimens we receive will only be identified with a code. We will keep what we find out about your illness and our test results as private as the law allows. Your doctor will keep this Consent Form for his or her records, in a safe place. You will also get a copy. The Food and Drug Administration (FDA) and Department of Health and Human Services (DHHS) may review these research records. Your records may also be reviewed for audito purposes by authorized University of Miami employees or other agents who will be bound by the same provisions of confidentiality.

Rights
You can decide if you will be part of this study. You have the right to not participate in the study. Your lack of participation will not prejudice further/additional medical treatment. In other words, if you are not in this study, you will still get your normal medical care. The investigator reserves the right to remove you from the study without your consent at such time that they feel it is in the best interest for you medically, or for administrative reasons.

You may ask and will receive answers to any questions during the course of the study. If you have questions about your rights as a research participant you may contact Maria Arnold, Director of the University of Miami Human Subjects Research Office, at 305-243-3195. If you think you may have been hurt by being in this study or if you want to know more about your rights as part of this study, please call the CDC Deputy Director for Science's office at 1-800-584-8814. Please leave your name, phone number and state that you are calling about CDC Protocol #3792. Someone will call you back as soon as they can.

- ☐ I will allow my blood and urine to be collected and sent for ciguatera testing.
- ☐ I will allow any leftover blood and urine to be saved for future ciguatera testing.

Printed name

Signature Date

I observed the process of consent. The prospective participant read this form, was given the chance to ask questions, appeared to accept answers, and signed to enroll in the study.

Printed name

Signature Date

Print Name of Person Obtaining Consent Date

Person Obtaining Consent Date

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